510(K) Summary

K122772

1.1 Sponsor/Applicant Name and Address

Penumbra Inc.
1351 Harbor Bay Parkway
Alameda, CA 94502

NOV 20 2012

1.2 Sponsor Contact Information

Seth A. Schulman
Director, Regulatory Affairs
Phone: 510-748-3223
FAX: 510-217-6414
email: seth.schulman@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

September 7, 2012

1.4 Device Trade or Proprietary Name

DDC™ Catheters

1.5 Device Common/Usual or Classification Name

Catheter, Percutaneous (Product Code: DQY)

1.6 Identification of the Legally Marketed Devices to which Equivalence is Being Claimed:

Name of Predicate Device	Name of Manufacturer (Town, State)	510(k) Number
Penumbra PICA™ Catheter	Penumbra, Inc Alameda, CA	K093970
Penumbra System Reperfusion Catheters	Penumbra, Inc Alameda, CA	K072718, K090752 & K113163

1.7 Device Description:

The DDC™ Catheters are variable stiffness catheter with various diameters, a catheter shaft reinforced with a stainless steel or Nitinol coil, and have a radiopaque markerband on the distal end. They are available in various lengths. The DDC™ Catheters have a PTFE-lined lumen, which is coil re-enforced, flexible, and hydrophilically coated. The DDC™ Catheters are inserted through a guide catheter or vascular sheath, provide access to the target site and once in place, provides a reinforcing conduit for other intravascular devices. The devices are provided sterile and include a rotating hemostasis valve and tip shaping mandrel. The DDC™ Catheters will be available in various configurations to allow physician ease of device tracking to the target site

1.8 Intended Use:

The DDC™ Catheters are indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

1.9 Comparison to Predicate Devices

The DDC™ Catheters include design modifications that enable improved trackability and therapeutic device deliverability to the vasculature. This submission also includes larger lumen catheters in various lengths compared to the predicate PICA™ Catheter.

	Penumbra System Reperfusion Catheters	PICA™ Catheter	Subject DDC™ Catheters

	Penumbra System Reperfusion Catheters	PICA™ Catheter	Subject DDC™ Catheters
Indication	The Penumbra System™ is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset.	The PICA™ Catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.	SAME (PICA)
Materials			
- Catheter Shaft/Hub	Nylon, PTFE, Polyurethane, Polycarbonate, hydrophilic coating	Nylon, PTFE, Polyurethane, Polycarbonate, hydrophilic coating	SAME
- Catheter shaft support	Stainless Steel/Nitinol	Stainless Steel	SAME (Penumbra System Reperfusion Catheters)
- Catheter Markerband	Platinum / Iridium	Platinum / Iridium	SAME
- Packaging	Tyvek/Mylar pouch, polyethylene hoop paper packaging card, SBS carton	Tyvek/Mylar pouch, polyethylene hoop paper packaging card, SBS carton	SAME
Sterilization	EtO	EtO	SAME
Shelf-Life	36 Months	36 Months	SAME

1.10 Summary of Non-clinical Data:

Biocompatibility tests conducted for the DDC™ Catheters were selected in accordance with ISO-10993 -1 guidelines (Biological Evaluation of Medical Devices) for external communicating devices contacting circulating blood. All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices.

Non-clinical testing found the DDC™ Catheters to be biocompatible and non-pyrogenic. The physical, mechanical and performance testing of the subject DDC™ Catheters demonstrate that the product is safe and effective for its labeled indications and is Substantially Equivalent to the currently marketed predicate devices.

Table 1: DDC Performance Testing

Attribute	Acceptance Criteria	Results

Attribute	Acceptance Criteria	Results
DDC must be compatible with 6F sheath	100% Pass	100% Pass
DDC tracking over 0.038" guidewire	100% Pass	100% Pass
0.038" Guidewire Compatible	100% Pass	100% Pass
Hub Transition	100% Pass	100% Pass
Microcatheter compatibility	100% Pass	100% Pass
Microcatheter friction	100% Pass	100% Pass
Microcatheter support	100% Pass	100% Pass
0.038in guidewire compatibility (Friction Force) (DDC 5MAX only)	100% Pass	100% Pass
Torsion (DDC 4MAX only)	100% Pass	100% Pass

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 20, 2012

Penumbra, Inc.
c/o Mr. Seth A. Schulman
Director, Regulatory Affairs
1351 Harbor Bay Parkway
Alameda, CA 94502

Re: K122772
Trade/Device Name: DDC™ Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: September 7, 2012
Received: September 10, 2012

Dear Mr. Schulman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K122772

Device Name: DDC™ Catheters

Indications For Use:

The DDC™ Catheters are indicated for the introduction of interventional devices into the peripheral and neurovasculature.

Prescription Use __XX__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number _____K122772_____